REMARKS

I. Status of the Application

Claims 1-40 are presently pending in the application. Claims 8-26 and 36 have been withdrawn by the Examiner. Claims 1, 4, 5, and 37 have been amended to correct minor grammatical errors. Support for new claim 41 can be found at claim 4 of the specification as filed. The amendments introduce no new matter.

Claims 1-5, 28, 32 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn US 5,129,889. Claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Hahn. Claims 6-7, 30-31 and 38-40 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn. Claim 27 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn in view of Jackson US 2003/0134811. Claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn in view of Noda US 6,669,711. Claims 33-34 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn in view of Goldsmith US 5,026,378.

Applicants respectfully request reconsideration of the foregoing claims in view of the amendments and remarks.

II. Claims 1-5, 28, 32 and 37 Are Not Anticipated By Hahn

At page 4 of the present office action, claims 1-5, 28, 32 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn US 5,129,889. At page 5 of the present office action, claim 35 stands rejected under 35 U.S.C. § 102(b) as being anticipated by, or under 35 U.S.C. §103(a) as being obvious over Hahn US 5,129,889. The Examiner believes that Hahn teaches each and every limitation of claims 1-5, 28, 32, 35 and 37. Applicants respectfully traverse the Examiner's rejection.

For the reasons presented in applicants' Amendment and Response to Office Action filed July 6, 2009, Hahn fails to anticipate the pending claims because Hahn fails to teach or disclose a drain comprising an elastic biocompatible, biodegradable synthetic polymer, which polymer has at least one softening point of at most mammalian body temperature and an elastic modulus of up to 120 MPa.

At page 2 of the office action the Examiner states that:

> Hahn teaches that the catheter, which is capable of being used as a drain, comprises lactide polyester, which is positively claimed in claim 5 by the Applicant, thus the Hahn device necessarily exhibits the claimed material properties.

Applicants respectfully disagree with the Examiner. Hahn discloses a polylactide which may or may not be understood by one of skill in the art as being a lactide polyester, as claimed. But certainly Hahn provides no written description of the molecular structure of its polylactide, its molecular weight, chirality, repeating units, etc. all of which reflect structure that define the properties of the molecule. One of skill in the art has no basis to make the leap from the term "polylactide" to polylactide with any specific elastic modulus. One of skill hearing the term polylactide would have no idea of the specific structure or properties of the molecule, except that there are many lactide units. One of skill would understand that polylactides can have many different properties depending on structure, molecular weight, repeating units etc., including elastic modulus, crystallinity, glass transition temperature, melting temperature etc. Without more, one of skill would not be able to say with any reasonable degree of certainty that a "polylactide" necessarily has any particular structure or property and certainly not the claimed elastic modulus of up to 120 MPa. The Examiner has no factual evidence to the contrary.

Instead, the Examiner relies on legal argument by citing *In re Spada* for the rationale that "discovery of a new property for a previously known composition canot impart patentability of

the known composition." However, the facts of the present application are sufficiently dissimilar from those cases to prevent application of the rationale used by the court. At the outset, applicants are not patenting a composition as in *Spada*. Applicants are patenting a drain. This is enough basis to prevent application of *Spada*. But there is more. *In re Spada* involved two unique products composed of polymers of the same monomers in overlapping ratios of components. 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). In *Spada*, the actual chemical composition of each product was known and all that differed was the ratio of components. This is very different from the Hahn which provides no written description of the chemical composition or structure of the polylactide. Structures within the term polylactide can vary widely and exhibit very different properties. This is why applicants claim an elastic synthetic polymer and one having an elastic modulus of up to 120 MPa to distinguish from elastic synthetic polymers having an elastic modulus outside that range. The polylactide of Hahn does not ***necessarily*** exhibit the material properties of the pending claims.

Since the Examiner cannot identify written description within Hahn of the structure or properties of the polylactide, the Examiner has effectively relied on an inherency argument that the material properties of "lactide polyester" are necessarily exhibited by "polylactide." However, "[i]nherent anticipation requires that the missing descriptive material [***i.e. an elastic modulus of up to 120 MPa***] is 'necessarily present,' not merely probably or possibly present, in the prior art." *In re Robertson*, 169 F.3d 743,745 (Fed. Cir. 1999). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. "[T]he examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic ***necessarily*** flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). There

is no evidence within Hahn or identified by the Examiner that the synthetic polymer ***necessarily*** has at least one softening point of at most mammalian body temperature and an elastic modulus of up to 120 MPa as required by the claim.

Hahn provides no written description of any structure or properties of any synthetic polymer. Specifically, Hahn provides no description of the chemical structure or composition, molecular weight, melting temperature, Young's modulus, or any other material property of any synthetic polymer. The only facts of record regarding MPa for polylactide are in applicants' last submission where the polylactide of Hahn is identified as having an elastic modulus of 400-2800 MPa, which is at least 3 times larger than the maximum 120 MPa of the pending claims. The Examiner has not disputed this submission, and this evidence of record distinguishes the claimed synthetic polymer from the polylactide of Hahn.

There are no facts of record on which the Examiner can conclude that the polylactide of Hahn has the claimed elastic modulus. It is just as likely that the polylactide of Hahn may have a completely different elastic modulus, such as between 400-2800 MPa. In fact, applicants have asserted as much without traversal by the Examiner. The Examiner has not explained why the polylactide of Hahn does not have an elastic modulus of between 400-2800 MPa or why applicants' representation is not to be believed. When this occurs, a rejection of anticipation based on inherency principles cannot be supported, and the Examiner cannot shift the burden to the applicant because the Examiner has not met her initial burden to demonstrate inherency, or otherwise demonstrate that the polylactide of Hahn does not have an elastic modulus of between 400-2800 MPa, as asserted by applicants.

Additionally, the biodegradable catheter of Hahn has a unique purpose from that of the claimed drain so it would be likely that the synthetic polymers would have different material

properties. The purpose of the biodegradable catheter of Hahn is to provide a continuous anesthesia epidural. See Abstract of Hahn. The catheter is then intended to be removed when the epidural is complete. The catheter is NOT intended to remain in the body for any prolonged period of time. There is no evidence of record that a synthetic polymer having an elastic modulus of up to 120 MPa could perform the function of Hahn. Hahn's catheter is biodegradable, but only as a precaution should a piece break when being removed. See col. 5, lines 42-44. This is strong evidence that the polylactide of Hahn is rigid and not elastic, as an elastic material may not break as easily as a rigid material. Further, Hahn would not use an elastic material since such a material would be more difficult to remove from an individual, or at least more uncomfortable to remove, as the catheter would likely stretch to a certain extent when being pulled. Removal of a rigid tube would provide greater patient comfort. This aspect alone counsels against a reading of Hahn's polylactide being elastic or having an elastic modulus of up to 120 MPa.

The biodegradable drain of the pending application is intended to be left inside the body for an extended period of time, specifically to "remain functional in the body or antrum orifice for the duration of the prescribed, clinical appropriate period of time to accomplish the predetermined therapeutic purpose." See page 5, lines 7-9 of the pending application. In fact, the drains are intended to maintain their functional properties for 2 to 12 weeks or in some situations for several months. See page 16, lines 13-15 and page 17, lines 22-24. This is not true with common catheters. The catheter of Hahn is not the claimed drain.

Since Hahn fails to teach each and every limitation of claims 1-5, 28, 32, 35 and 37, Hahn cannot anticipate, or render obvious, those claims. Accordingly, applicants respectfully request that the rejection of the claims based on Hahn be withdrawn.

III. Claims 6-7, 30-31 and 38-40 Are Not Obvious Over Hahn

At page 6 of the present office action, claims 6-7, 30-31 and 38-40 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

As previously discussed, Hahn fails to provide any written description regarding specific structures or properties of synthetic polymers. Specifically, Hahn fails to teach or suggest a synthetic polymer having an elastic modulus of up to 120 MPa. In fact, Hahn teaches that its catheter is not elastic but is "characterized as being dimensionally and structurally stable." See Abstract of Hahn. The description of the catheter as being dimensionally and structurally stable implies that the catheter is certainly not elastic. This implication is further supported by the manner in which the epidural catheter is inserted into a human back, by being pushed through an epidural needle against resistance. See col. 5, lines 29-38. Applicants respectfully submit that synthetic polymers having an elastic modulus of up to 120 MPa are different from those used in the epidural catheter of Hahn.

With respect to claims 6 and 7 the Examiner states it would require only routine skills in the art to modify Hahn to obtain a polyester with a lactide content of 20-75 mol% and further where the fraction of the L-enantiomer or the D-enantiomer of the lactide is from 65-95 mol. A statement by the Examiner that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" are not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP 2143.01 citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). Hahn fails to provide any teaching with respect

to the chemical composition of any of the synthetic polymers disclosed. Hahn only discloses various possible combinations of materials to obtain the catheters. See claims 3 to 6 of Hahn.

One having routine skill in the art would first have to select the correct combination of materials from the disclosure of Hahn to obtain the specific polyester. Then that same person would have to experiment to obtain the correct combination of materials to obtain a lactide content of 20-75 mol % because there is no teaching in Hahn of any amount of a material in any combination.

With respect to claims 30 and 31 the Examiner states it would require only routine skill in the art to find the optimal length and thickness of the drain so that fluids can be properly drained outside the body. However, the Examiner has presented no arguments or identified any facts on which to conclude that one of skill would have altered the dimensions of the catheter to obtain the length and thickness recited in the pending claims.

KSR clearly requires the Examiner to provide "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" because "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR v. Teleflex*, 550 U.S. ___ (2007) at page 14.

Hahn fails to offer any suggestion on the length of the biodegradable catheter. The only discussion is that the catheter may display 5 cm distant markings (see col. 4, lines 64-66) and that upon insertion into the epidural space only 3-5 cm of catheter is advanced (see col. 5, lines 35-36). There is no teaching of a length of the catheter in its entirety; specifically there is no teaching of a catheter with a length of 3 to 300 mm. In fact, if 3-5 cm of catheter is advanced

into the epidural space upon insertion, there is no possibility of the catheter being 3 mm in length.

Further, Hahn fails to suggest a wall thickness of 0.05-5.0 mm. Rather, the size of the epidural catheter is limited by the epidural needle used to insert the catheter.

> From a practical standpoint, there is a ***certain limit for the size*** of the epidural needle 20 since the pain caused by inserting the epidural needle 20 into the patient should be minimized. Thus, the size of the epidural needle 20 is automatically fixed in a certain range, generally between 15 and 18 gauge, and preferably 17 gauge. Considering that a 17-gauge needle has an inner diameter of about 1.17 mm...it is desired that the size of tube 10 be in a range of about 0.6 to about 1.0 mm, preferably 0.8 mm as an inner diameter thereof and 1.0 mm as an outer diameter.

There is no teaching or suggestion to modify the catheter to have a wall thickness of 0.05-5.0 mm and if the wall thickness was 5.0 mm it would be larger than the diameter of the epidural needle it is to be inserted through. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01 citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Accordingly, applicants respectfully request that the rejection of claims 6-7, 30-31, and 38-40 should be reconsidered and withdrawn.

IV. Claim 27 Is Not Obvious Over Hahn and Jackson

At page 8 of the present office action, claim 27 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn and Jackson. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, Hahn fails to teach or suggest all of the limitations of claim 27. Jackson, which is relied upon for the teaching of anti-inflammatory agents mixed into

a biodegradable polymer, fails to cure the deficiencies of Hahn. Accordingly, applicants respectfully request that the rejection of claim 27 based on Hahn and Jackson be withdrawn.

V. Claim 29 Is Not Obvious Over Hahn and Noda

At page 8 of the present office action, claim 29 stands rejected under 35 U.S.C. § 103(a) as being obvious over Hahn and Noda. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, Hahn fails to teach or suggest all of the limitations of claim 29. Noda, which is relied upon for the teaching of a nasal drain, fails to cure the deficiencies of Hahn. Further, one of skill in the art of biodegradable drains would not look to Noda because Noda discloses a surgical balloon that "prevents a liquid or gas from flowing from one area of the body to another area." See col. 2, lines 49-52. This is the opposite desired effect of the disclosed drain. Accordingly, applicants respectfully request that the rejection of claim 29 based on Hahn and Noda be withdrawn.

VI. Claims 33-34 Are Not Obvious Over Hahn and Goldsmith

At page 8 of the present office action, claims 33-34 stand rejected under 35 U.S.C. § 103(a) as being obvious over Hahn and Goldsmith. Applicants respectfully traverse the Examiner's rejection as to the amended claims now presented.

For the reasons discussed above, Hahn fails to teach or suggest all of the limitations of claims 33-34. Goldsmith, which is relied upon for the teaching of a funnel shape, fails to cure the deficiencies of Hahn. Accordingly, applicants respectfully request that the rejection of claims 33-34 based on Hahn and Goldsmith be withdrawn.

VII. Conclusion

Having addressed all outstanding issues, applicants respectfully request reconsideration and allowance of this case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below. The Commissioner is authorized to apply any additional charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

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